

# Skin antiseptic trial for insertion of central venous catheters in neonates

<b>Submission date</b> 07/07/2016	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 14/07/2016	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 01/11/2023	<b>Condition category</b> Infections and Infestations	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

When in intensive care, many premature babies need to have a special catheter (thin tube) put into one of their larger (central) veins to give liquid nutrition safely to help them grow (percutaneous central venous catheter, PCVC). These catheters are vital, but can sometimes become infected. Catheter infection is a dangerous complication. Cleaning a baby's skin with antiseptic before inserting a catheter is one important way to prevent catheter infection. Some antiseptics may be better at preventing catheter infection than others, as well as being safer to use on the thin vulnerable skin of premature babies. Doctors don't yet know which antiseptics are safest and best to use in premature babies. It is therefore important to find out which antiseptics are best for use in premature babies. Chlorhexidine and alcohol and two different antiseptics that are commonly used in neonatal units to clean the skin of babies before catheters are inserted. Sometimes these particular antiseptics are used individually and sometimes they are used in combination. In the future a large study will be conducted to compare two forms of these antiseptics for cleaning the skin in premature babies, to find out if chlorhexidine on its own is just as good at cleaning a baby's skin as chlorhexidine mixed with alcohol. The findings will guide doctors in deciding which antiseptic to choose for skin preparation in premature babies and will show if alcohol is important to use along with chlorhexidine, or whether alcohol can be avoided. The aim of this study is to investigate whether a large scale study looking at the effectiveness and safety of these antiseptic solutions for cleaning skin before PCVC insertion is feasible.

### Who can participate?

Premature babies born at least six weeks early who need a PCVC placed as part of their routine care.

### What does the study involve?

Babies in the study are randomly allocated to one of two groups, who each have the skin cleaned with one of two antiseptics just before the catheter is inserted and again just before the catheter gets removed. Three quarters of the babies are randomly allocated to receive an chlorhexidine mixed with alcohol (70% isopropyl alcohol-based 2% chlorhexidine gluconate) and one quarter to receive chlorhexidine antiseptic (2% chlorhexidine gluconate). The skin and the catheters are tested after removal to see if they ended up coated with (colonised by) bacteria by

the time of catheter removal, because catheter colonisation is a known major risk factor for infection. The number of babies recruited to the study and who stayed in until the end of the study are also recorded to gather information about how many babies are needed to conduct a larger study.

What are the possible benefits and risks of participating?

It is not known whether there will be any benefits of taking part in this study, however if the antiseptic the participants receive is more effective than the one normally used for central venous catheter insertion, then they may benefit from a decreased risk of catheter infection. Both antiseptic solutions chosen for use in this study are already commonly used in premature babies in Europe and America. Skin reactions such as redness and chemical burns have occasionally been reported with both of these antiseptics. The risk of skin reactions is increased when excess antiseptic solution is used or when it is in prolonged contact with the skin in very premature babies.

Where is the study run from?

Norfolk and Norwich University Hospital, Norwich (lead centre) and Medway Maritime Hospital, Gillingham (UK)

When is the study starting and how long is it expected to run for?

May 2015 to March 2019

Who is funding the study?

National Institute for Health Research (UK)

Who is the main contact?

1. Dr Paul Clarke (scientific)

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2. Mrs Tracy Oliver (public)

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**Study website**

<http://www.npeu.ox.ac.uk/arctic>

## Contact information

**Type(s)**

Scientific

**Contact name**

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**Type(s)**  
Public

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## Additional identifiers

**EudraCT/CTIS number**  
2015-000874-36

**IRAS number**

**ClinicalTrials.gov number**  
N/A

**Secondary identifying numbers**  
19899

## Study information

**Scientific Title**  
The efficacy and safety of two topical antiseptic solutions for skin disinfection prior to percutaneous central venous catheter insertion in preterm neonates: a feasibility study

**Acronym**  
ARCTIC

**Study objectives**  
The aim of this study is to investigate the feasibility of conducting a full scale trial of the efficacy and safety of two topical antiseptic solutions for skin disinfection prior to percutaneous central venous catheter insertion in preterm neonates.

**Ethics approval required**  
Old ethics approval format

**Ethics approval(s)**  
East of England - Cambridge South Research Ethics Committee, 30/10/2015, ref: 15/EE/0345

**Study design**

Randomised; Interventional; Design type: Treatment, Diagnosis, Prevention, Process of Care, Drug, Management of Care, Active Monitoring

**Primary study design**

Interventional

**Secondary study design**

Randomised controlled trial

**Study setting(s)**

Hospital

**Study type(s)**

Treatment

**Participant information sheet**

See trial outputs table

**Health condition(s) or problem(s) studied**

Specialty: Children, Primary sub-specialty: Neonatal

**Interventions**

Preterm infants born at <34 weeks' gestation who are undergoing planned insertion of a percutaneously-inserted central venous catheter will be randomised to receive one of two commonly used topical disinfection agents for skin antisepsis: aqueous-based 2% chlorhexidine gluconate (2%CHG), or 70% isopropyl alcohol-based 2% chlorhexidine gluconate (70%IPA/2% CHG). The interventional antiseptic for skin disinfection will be used at the time of catheter insertion and also at removal. For both arms, follow up will proceed from catheter insertion up until 48 hours post catheter removal. Randomisation will use a web-based facility and a stratified block randomisation method to stratify groups by birth gestation and within neonatal centre. Randomisation will provide a 3:1 allocation ratio in favour of the alcohol-based antiseptic.

Follow up of study participants involves daily assessment of skin integrity of the catheter insertion site, daily evaluation of sepsis, and recording of concomitant antibiotics/antifungals until 48 hours post catheter removal. At catheter removal one exit-site skin swab and two catheter segments (proximal portion and a catheter tip portion) will be obtained and will be sent for microbiological culture.

**Intervention Type**

Other

**Primary outcome measure**

Proportion of babies in the 70%IPA/2%CHG arm with catheter colonisation as determined by culture of catheter segments taken at the time of catheter removal.

**Secondary outcome measures**

1. Rates of recruitment and retention to the study and factors affecting these are determined by proportions of eligible patients enrolled and proportion of enrolled subjects completing the study, and collection of the views of parents and clinicians on factors affecting recruitment and

retention

2. Proportion of infants with positive exit-site skin swabs are measured by microbiological culture of catheter segments taken at catheter removal
3. Number and type of catheter segments culture positive are measured by microbiological culture of the catheter segments (proximal portion and the tip portion) taken at catheter removal
4. Bacterial species (typed via molecular methods using Next Generation sequencing) of isolates identified on any positive blood culture obtained during the indwelling of the catheter and up until 48 hours post catheter removal, and any positive exit-site skin swab or positive catheter segment culture taken at the time of catheter removal
5. Proportion of infants undergoing an infection screen in the period between catheter insertion and 48 hours post-catheter removal that meets case definition for definite catheter-related sepsis
6. Proportion of infants with positive blood culture from any infection screen in the period between catheter insertion and 48 hours post-catheter removal that meets definition for catheter-associated sepsis
7. Proportion of infants completing study with complete data for the primary outcome and proportions of infants with missing data collection forms
8. Daily skin morbidity scores are assessed using a validated neonatal skin condition scoring system in the period between catheter insertion and 48 hours post-catheter removal

**Overall study start date**

01/01/2015

**Completion date**

15/10/2019

## **Eligibility**

**Key inclusion criteria**

1. Preterm infants born at <34 weeks' gestation
2. Requiring routine insertion of a PCVC for parenteral nutrition
3. No new suspected sepsis with commencement of antibiotics occurring within the 48 hours preceding planned catheter insertion
4. No other indwelling PCVC already in situ

**Participant type(s)**

Patient

**Age group**

Neonate

**Sex**

Both

**Target number of participants**

Planned Sample Size: 110; UK Sample Size: 110

**Total final enrolment**

116

**Key exclusion criteria**

1. No realistic prospect of survival in the short term
2. Life-threatening congenital abnormality
3. Underlying skin condition
4. Already has another indwelling PCVC in situ or was previously enrolled into the study in respect of an earlier PCVC episode
5. Positive blood culture (BC) within the past 7 days without a subsequent negative blood culture result
6. Antibiotic treatment commenced for suspected sepsis within the preceding 48 hours

**Date of first enrolment**

13/03/2017

**Date of final enrolment**

27/07/2018

**Locations****Countries of recruitment**

England

United Kingdom

**Study participating centre****Norfolk and Norwich University Hospital**

Neonatal Unit

Colney Lane

Norwich

United Kingdom

NR4 7UY

**Study participating centre****Medway Maritime Hospital**

Windmill Road

Gillingham

United Kingdom

ME7 5NY

**Sponsor information****Organisation**

Norfolk and Norwich University Hospitals NHS Foundation Trust

**Sponsor details**

Research and Development Office  
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**Sponsor type**

Hospital/treatment centre

**ROR**

<https://ror.org/01wspv808>

**Funder(s)****Funder type**

Government

**Funder Name**

National Institute for Health Research

**Alternative Name(s)**

National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

**Funding Body Type**

Government organisation

**Funding Body Subtype**

National government

**Location**

United Kingdom

**Results and Publications****Publication and dissemination plan**

1. The findings of this feasibility study will be shared with colleagues through presentations of the data to national and international scientific meetings
2. Findings will also be shared with the Bliss parents' support group, for dissemination to parents and professionals via the Bliss e-newsletter and website

3. Parents who allowed their baby's participation in the study will be given a summary report
4. Aim to publish findings in an Open Access peer-reviewed journal within 12 months of recruitment of the final participant

### Intention to publish date

31/12/2020

### Individual participant data (IPD) sharing plan

### IPD sharing plan summary

Available on request

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Protocol article</a>	protocol	19/02/2019		Yes	No
<a href="#">Basic results</a>		21/01/2020	10/11/2020	No	No
<a href="#">HRA research summary</a>			26/07/2023	No	No
<a href="#">Participant information sheet</a>	version 1.2	18/11/2016	30/08/2023	No	Yes
<a href="#">Results article</a>		31/10/2023	01/11/2023	Yes	No